

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK**

ELI DAYAN, individually on behalf of himself and :
all others similarly situated, :

Plaintiff,

V.

SWISS-AMERICAN PRODUCTS, INC.

Defendant.

[illegible]

Case No. 1:15-cv-06895-DLI-VMS

ORAL ARGUMENT REQUESTED

**MEMORANDUM OF LAW IN OPPOSITION TO
DEFENDANT’S MOTION TO DISMISS**

Jason P. Sultzer, Esq. (Bar ID #: JS4546)
Joseph Lipari, Esq. (Bar ID #: JL3194)
Jean M. Sedlak, Esq. (Bar ID #: JS4895)

Counsel for Plaintiff and the Class

TABLE OF CONTENTS

TABLE OF CONTENTS.....	I
TABLE OF AUTHORITIES.....	II-V
I. PRELIMINARY STATEMENT.....	1
1. Express Preemption.....	2
2. Implied Preemption.....	2
3. Magnuson-Moss Warranty Act.....	3
4. Scandalous Allegations.....	3
II. LEGAL ARGUMENTS.....	4
1. Well-Settled Case Law Undercuts Defendant’s Argument that Plaintiff’s Claims are Preempted.....	4
A. Plaintiff’s Claims are not Expressly Preempted.....	5
B. Plaintiff’s Claims are not Impliedly Preempted.....	9
2. Plaintiff’s MMWA Claims must Survive FRCP 12(b)(6) Scrutiny.....	13
3. Plaintiff has Plausibly Alleged Actionable Misconduct by Defendant.....	16
4. There is no Basis to Stay Discovery.....	18
III. CONCLUSION.....	19

TABLE OF AUTHORITIES

Cases

<i>Ashcroft v. Iqbal</i> , 556 U.S. 662, 129 (2009).....	17
<i>Bimont v. Unilever U.S., Inc.</i> , 2015 U.S. Dist. LEXIS 119908 (S.D.N.Y. Sept. 9, 2015).....	7
<i>Bowling v. Johnson & Johnson</i> , 65 F. Supp. 3d 371 (S.D.N.Y. 2014).....	7
<i>Bell Atl. Corp. v. Twombly</i> , 550 U.S. 544, (2007).....	17
<i>Birdsong v. Apple, Inc.</i> , 590 F.3d 955, 957 n.1 (9th Cir. 2009).....	15
<i>Brady v. Basic Research, L.L.C.</i> , 101 F. Supp. 3d 217, 234 (E.D.N.Y. 2015).....	13
<i>Buckman Co. v. Plaintiffs' Legal Comm.</i> , 531 U.S. 341 (U.S. 2001).....	12
<i>Burke v. Weight Watchers Int'l, Inc.</i> , 983 F. Supp. 2d 478, 480, 483 (D. N.J. 2013).....	12
<i>Chavis v. Fid. Warranty Servs., Inc.</i> , 415 F. Supp. 2d 620, 626 (D.S.C. 2006).....	15
<i>Chesney v. Valley Stream Union Free Sch. Dist. No. 24.</i> , 236 F.R.D. 113, 115 (E.D.N.Y. 2006).....	18
<i>Cipollone v. Liggett Group, Inc.</i> , 505 U.S. 504, 518, (1992).....	5
<i>Corra v. Energizer Holdings, Inc.</i> , 962 F. Supp. 2d 1207, (E.D. Cal. 2013).....	6, 8
<i>Diaz v. Local 338 of the Retail, Wholesale Dep't Store Union</i> , 2014 U.S. Dist. LEXIS 124394, *4 (E.D.N.Y. Sept. 3, 2014).....	18
<i>Dougherty v. Source Naturals, Inc.</i> , 2015 U.S. Dist. LEXIS 164117 (E.D. Mo. Dec. 8, 2015).....	11

<i>Eckler v. Neutrogena Corp.</i> , 238 Cal. App. 4th 433 (Cal. App. 2d Dist. 2015).....	6, 7
<i>Elkind v. Revlon Consumer Prods. Corp.</i> , 2015 U.S. Dist. LEXIS 63464 (E.D.N.Y. 2015).....	11
<i>Enobakhare v. Carpoint, LLC</i> , No. 08 Civ. 4798, 2010 U.S. Dist. LEXIS 141481, 2011 WL 703920, at *8 (E.D.N.Y. Jan. 10, 2011).....	13
<i>Fagan v. Neutrogena Corp.</i> , 2014 U.S. Dist. LEXIS 2795 (C.D. Cal. Jan. 8, 2014).....	8
<i>Galper v. JP Morgan Chase Bank, N.A.</i> , 802 F.3d 437, 444 (2d Cir. N.Y. 2015).....	4
<i>Gisvold v. Merck & Co.</i> , 62 F. Supp. 3d 1198 (S.D. Cal. 2014).....	6, 7
<i>Hishon v. King</i> , 467 U.S. 69, 73 (1984).....	17
<i>Hong Leong Finance Ltd. (Singapore) v. Pinnacle Performance Ltd.</i> , 297 F.R.D. 69, 72 (S.D.N.Y. 2013).....	18
<i>Hughes v. Ester C Co.</i> , 930 F. Supp. 2d 439, 461-62 (E.D.N.Y. 2013).....	17
<i>In re Frito-Lay N. Am., Inc.</i> , 2013 U.S. Dist. LEXIS 123824 (E.D.N.Y. Aug. 29, 2013).....	3, 14
<i>In re PepsiCo, Inc., Bottled Water Mktg. & Sales Practices Litig.</i> , 588 F. Supp. 2d 527, 532 (S.D.N.Y. 2008).....	5
<i>In re Sony Vaio Computer Notebook Trackpad Litig.</i> , No. 09-CV-2109 (BEN) (RBB), 2010 U.S. Dist. LEXIS 115142, at *4 (S.D. Cal. Oct. 28, 2010).....	15
<i>Jovel v. I-Health, Inc.</i> , 2013 U.S. Dist. LEXIS 139661, *12 (E.D.N.Y. Sept. 27, 2013).....	4
<i>Kanfer v. Pharmacare US, Inc.</i> , 2015 U.S. Dist. LEXIS 150105 (S.D. Cal. Nov. 4, 2015).....	15
<i>Kuns v. Ford Motor Co.</i> , 543 Fed. Appx. 572 (6th Cir. Ohio 2013).....	15

<i>L-7 Designs, Inc. v. Old Navy, LLC</i> , 647 F.3d 419 (2d Cir. N.Y. 2011).....	16
<i>Lombardo v. Johnson & Johnson Consumer Cos.</i> , 2014 U.S. Dist. LEXIS 156881, (S.D. Fla. Sept. 9, 2014).....	5, 8
<i>Mee v. I A Nutrition, Inc.</i> , 2015 U.S. Dist. LEXIS 63038 (N.D. Cal. May 13, 2015).....	11
<i>Medtronic, Inc. v. Lohr</i> , 518 U.S. 470 (U.S. 1996).....	12
<i>Palm Beach Strategic Income v. Stanley P. Salzman, P.C.</i> , 2011 U.S. Dist. LEXIS 46867 (E.D.N.Y. May 2, 2011).....	3, 16
<i>Pangburn v. Culbertson</i> , 200 F.3d 65, 70 (2d Cir. 1995).....	19
<i>Quinn v. Walgreen Co.</i> , 958 F. Supp. 2d 533, 544 (S.D.N.Y. 2013).....	17
<i>Rosen v. St. Jude Med., Inc.</i> , 41 F. Supp. 3d 170, 186 (N.D.N.Y. 2014).....	12
<i>Salazar v. Honest Tea, Inc.</i> , 74 F. Supp. 3d 1304, 2014 U.S. Dist. LEXIS 83164, 2014 WL 2593601, at *1, 6 (E.D.Cal. June 10, 2014).....	11
<i>Samuels v. Greenberg</i> , 2015 U.S. Dist. LEXIS 128221 (E.D.N.Y. Sept. 23, 2015).....	16
<i>Silverman v. Unum Group</i> , 2015 U.S. Dist. LEXIS 99714 (E.D.N.Y. July 30, 2015).....	16
<i>Smith v. Allmax Nutrition, Inc.</i> , 2015 U.S. Dist. LEXIS 171897 (E.D. Cal. Dec. 23, 2015).....	9, 11
<i>Spencer Trask Software and Information Services. LLC v. RPost International Ltd</i> , 206 F.R.D. 367, 368 (S.D.N.Y. 2002).....	18
<i>Szymczak v. Nissan N. Am., Inc.</i> , 2011 U.S. Dist. LEXIS 153011, at *18 (S.D.N.Y. Dec. 16, 2011).....	17

<i>Vital v. One World Co.</i> , 2012 U.S. Dist. LEXIS 186203, at *2, 13-18 (C.D. Cal. November 30, 2012).....	12
<i>Weisblum v. Prophase Labs, Inc.</i> , 88 F. Supp. 3d 283 (S.D.N.Y. 2015).....	15

Statutes

15 U.S.C. § 2310(d)(1).....	13
15 U.S.C. § 2301(6)(A).....	13
21 C.F.R. § 201.6(a).....	5
21 C.F.R. § 701.1(a).....	5
21 C.F.R. § 201.327.....	6
21 C.F.R. § 101.9(g)(2).....	9, 10, 12
21 C.F.R. § 101.9 (c)(1)(i).....	12
21 C.F.R. § 101.36 (f)(1).....	10
21 U.S.C. § 379r.....	8
21 U.S.C. §§ 379r(a), 379s(a).....	5
21 U.S.C §§ 379r(a)(2), 379s(a).....	5, 8
21 U.S.C. §§ 379r(f).....	5
21 C.F.R. § 201.327(g).....	6
FRCP 12(b)(6).....	1, 2, 13, 14, 16
FRCP R. 8.....	1
FRCP 12(c).....	16
FRCP 15 (a)(2).....	19
FRCP 26(c).....	18
GBL §349.....	2, 8, 13
GBL §350.....	2, 8, 13

I. PRELIMINARY STATEMENT

Given defendant's representations that its sunscreen has a sunburn protection factor ("SPF") of 45, plaintiff Eli Dayan and consumers across the country have been induced to purchase defendant's sunscreen. But, defendant's representations are demonstrably false and misleading. In fact, as alleged and supported in plaintiff's Complaint, the product's true SPF value is only 18 -- less than half of the SPF value that defendant advertises and represents. Defendant's conduct is potentially hazardous to the health of its consumers, who reasonably believe and act upon the reasonable belief that they have a greater degree of sun protection than they actually have.

Far from being a "lawyer-driven" class action solely reliant upon "a *Consumer Report* article," as defendant contends, this is a case in which a consumer, who was not adequately protected from cancer-causing ultraviolet radiation, brought suit after FDA-compliant,¹ independent testing confirmed that defendant lied about its sunscreen's SPF value. And, notwithstanding defendant's breathless assertions about it being "shocking, but not surprising" that plaintiff did not reference defendant's own flawed and dubious studies in the Complaint, FRCP R. 8 and FRCP R. 12 (b) (6) jurisprudence dictate that a plaintiff is only required to allege and support the grounds for his entitlement to relief. Plaintiff has done so in this case. Simply put, the only thing that is legitimately "shocking" about this case is defendant's ongoing deception about SPF values despite escalating skin cancer rates in the United States.

In its motion to dismiss, defendant argues that plaintiff's claims are preempted by the FDCA and that, aside from preemption, there are independent grounds to dismiss plaintiff's

¹ Defendant states throughout its brief that plaintiff did not attach the test that yielded the SPF 18 result and that the test on its face does not comply with FDA requirements (i.e. 10-member panel). Both statements are false. See Exhibit B, R. Doc. 1-3, page 5 of 81, page 6 of 81, and page 13 of 81.

claims.² But, as set forth below, plaintiff's complaint is well-pled and must survive 12(b) (6) scrutiny for, *inter alia*, the following reasons:

1. **Express Preemption:** Plaintiff's Complaint alleges that independent testing -- which was compliant with the FDA testing protocol for SPF validation -- revealed that defendant has scammed and is continuing to scam consumers into paying premium prices for a product labeled as SPF 45 when in actuality the product's true SPF value is only 18. Plainly, plaintiff's Complaint does not seek to impose labeling or advertising requirements greater than those imposed by the FDCA. Nor does plaintiff's Complaint seek to require defendant to include additional or qualitatively different information on a federally approved label. Rather, plaintiff's state law claims parallel and are consistent with FDCA requirements inasmuch as plaintiff has asserted that defendant failed to accurately set forth the sunscreen's true SPF value. And, plaintiff's claims are predicated on violations of obligations imposed by, *inter alia*, GBL 349 and 350.
2. **Implied Preemption:** Plaintiff's claims are premised on conduct that both (1) violates the FDCA and (2) gives rise to recovery under state law even in the absence of the FDCA. In its moving papers, defendant has cherry-picked phrases from inapposite cases in support of its argument that plaintiff's claims are impliedly preempted simply because the FDA has issued a testing protocol for determining SPF values. But, there are numerous, analogous cases standing for the proposition that there can be no finding of preemption within the context of a FRCP 12 (b) (6) where a plaintiff alleges he followed FDA testing protocols in support of his claims that defendant's labeling is violative of the FDCA and parallel state consumer protection laws. Here, a plain review of plaintiff's

² Defendant also argues that discovery should be stayed pending resolution of the motion to dismiss. But, as set forth below, there is no basis for a stay.

Complaint reveals that plaintiff pled and supported his averment that an independent laboratory conducted tests that were “compliant with the FDA testing protocol for SPF validation.”

3. **Magnuson-Moss Warranty Act:** Defendant -- citing *In re Frito-Lay N. Am., Inc.*, 2013 U.S. Dist. LEXIS 123824 (E.D.N.Y. Aug. 29, 2013) -- asserts the tenuous argument that plaintiff’s MMWA claims relative to the metric “SPF 45” are somehow analogous to Frito Lay’s “All Natural” claims on a bag of its potato chips. Needless to say, unlike the phrase “All Natural,” the metric “SPF 45” does indeed represent that the product will meet a specified level of performance over time. More specifically, as explained by the FDA, and as set forth in the Complaint, an SPF value refers to: “the amount of ultraviolet (UV) radiation exposure it takes to cause sunburn when a person is using a sunscreen in comparison to how much UV exposure it takes to cause a sunburn when they do not use a sunscreen. The product is then labeled with the appropriate SPF value indicating the amount of sunburn protection provided by the product.” (Exhibit A, Complaint, Paragraph 7, footnote 3).

4. **Scandalous Allegations:** Employing hyperbole and impugning both plaintiff and his counsel, defendant argues that because it has its own test reports, the plaintiff’s allegations are therefore “scandalous” and “spurious,” and thus plaintiff’s claims should be dismissed. In support of this argument, defendant cites a case³ in which the court found that a plaintiff and its counsel actively misled the court about the source of a wire transfer and apparently had the correct wire transfer information in its possession at the

³ *Palm Beach Strategic Income v. Stanley P. Salzman, P.C.*, 2011 U.S. Dist. LEXIS 46867 (E.D.N.Y. May 2, 2011).

time it actively misled the court. Needless to say, this case is inapposite. As set forth in the Complaint, plaintiff's tests were performed by an independent laboratory and comply with FDA testing protocols. It is well-established that a plaintiff is only required to *plausibly* allege that a manufacturer's product statements are false. Further, relevant case law indicates that whether plaintiff's tests and studies support his claims is an issue of fact that cannot be resolved within the context of a motion to dismiss. If the defendant wishes to argue that plaintiff's tests are methodologically unsound -- which they are not -- defendant may do so within the context of a post-discovery *Daubert* motion.

II. LEGAL ARGUMENTS

1. Well-Settled Case Law Undercuts Defendant's Argument that Plaintiff's Claims are Preempted

The Second Circuit has instructed that when a court is "considering a preemption argument in the context of a motion to dismiss," it must view "the factual allegations relevant to preemption . . . in the light most favorable to the plaintiff." *Galper v. JP Morgan Chase Bank, N.A.*, 802 F.3d 437, 444 (2d Cir. N.Y. 2015). And, "a district court may find a claim preempted only if the facts alleged in the complaint do not plausibly give rise to a claim that is not preempted." *Id.* Moreover, it is well-settled that "in fields traditionally occupied by the states, such as health and safety regulation, there is a strong presumption against federal preemption." *Jovel v. I-Health, Inc.*, 2013 U.S. Dist. LEXIS 139661, *12 (E.D.N.Y. Sept. 27, 2013). To overcome this strong presumption, defendant must demonstrate: (1) Congress or an agency with delegated authority has expressly stated that preemption is intended ("express preemption"), or (2) Congress intended to occupy the field ("field preemption"), or (3) state causes of action conflict with federal objectives to such a degree that harmony between the two becomes

impossible ("conflict preemption"). *Id.* at *13. Defendant cannot overcome this strong presumption.

A. Plaintiff's Claims are not Expressly Preempted

The FDA classifies sunscreens as over-the-counter drugs regulated by the Food, Drug, and Cosmetic Act ("FDCA"). *Lombardo v. Johnson & Johnson Consumer Cos.*, 2014 U.S. Dist. LEXIS 156881, *4 (S.D. Fla. Sept. 9, 2014). The FDCA expressly preempts any state law that "relates to the regulation of a drug" or "the labeling or packaging of a cosmetic," that is "different from or in addition to, or that is otherwise not identical with, a requirement under this chapter." 21 U.S.C. §§ 379r (a), 379s(a). Corresponding FDA regulations state: "Among representations in the labeling of a drug which render such drug misbranded is a false or misleading representation with respect to another drug or a device or a food or cosmetic." 21 C.F.R. § 201.6(a), *see also* 21 C.F.R. § 701.1(a). Thus, while states may not expand on the requirements in the FDCA, they may adopt regulations that are identical to the FDCA's requirements.⁴ *See* 21 U.S.C. §§ 379r(a)(2), 379s(a); *In re PepsiCo, Inc., Bottled Water Mktg. & Sales Practices Litig.*, 588 F. Supp. 2d 527, 532 (S.D.N.Y. 2008) ("[S]tate law causes of action are not preempted where they merely provide a damages remedy for claims premised on a violation of federal law that does not itself provide a private right of action, but are preempted where they impose obligations not imposed by federal law."). Indeed, 21 U.S.C. §§ section 379r(f) explicitly states that "[n]othing in this section shall prevent a State or political subdivision thereof from enforcing, under any

⁴ Furthermore, where Congress enacts an express preemption clause, the presumption against preemption requires courts to read the clause narrowly. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 518, (1992).

relevant civil or other enforcement authority, a requirement that is identical to a requirement in this chapter."

Defendant argues that plaintiff's claims are expressly preempted inasmuch as they seek to impose labeling and advertising requirements that go beyond the requirements imposed by the FDA Final Rule⁵. In support of this argument, defendant relies on California cases such *Eckler v. Neutrogena Corp.*, 238 Cal. App. 4th 433 (Cal. App. 2d Dist. 2015) and *Gisvold v. Merck & Co.*, 62 F. Supp. 3d 1198 (S.D. Cal. 2014). But, these cases undercut defendant's argument and show exactly why plaintiff's claims in the matter *sub judice* are not expressly preempted.

In *Eckler*, plaintiff alleged that the manufacturer violated California law because consumers were likely to be misled about the efficacy of products with an SPF value greater than 50.⁶ The California Court of Appeal held that plaintiff's claims were preempted because, *inter alia*, plaintiff "seeks disclosure language added to Neutrogena's product label and a corrective advertising campaign" and plaintiff's "proposed disclaimer plainly adds to and is not identical with the FDA's requirements." *Eckler*, supra at 458. Here, and in stark contrast to *Eckler*, plaintiff is not asking for additional or qualitatively different language to be added to the labeling. Rather, plaintiff is alleging that defendant has falsely represented the SPF value of its product (i.e. SPF 45 is, in actuality SPF 18). (Exhibit A, Complaint, Paragraphs 17, 20; Exhibit

⁵ Insofar as defendant is argue that 21 C.F.R. § 201.327 encompasses the general duty not to engage in false or misleading advertising — and preempts state law claims on this issue, courts have held that "this argument is...without merit." See *Corra v. Energizer Holdings, Inc.*, 962 F. Supp. 2d 1207, 1215 (E.D. Cal. 2013) ("as to claims on sunscreen products considered to be false and/or misleading, the C.F.R. prefaces the (brief) list of delineated claims with the phrase "[t]hese claims include but are not limited to[.]" 21 C.F.R. § 201.327(g). The inclusion of this phrase means the list of delineated claims is not exclusive to other claims, and, in the Court's view, clearly evinces no intent to preempt state consumer fraud claims.")

⁶ Plaintiff also alleged that defendant violated state and federal law by using the descriptions "sunblock," "waterproof," and "sweatproof" before the date when the federal Food and Drug Administration (FDA) required the manufacturer to stop using those descriptions. But, the court rejected this argument and held that "Placing into commerce a package of sunscreen bearing the terms "waterproof," "sweatproof," and "sunblock" became non-compliant with a federal regulation for the first time on December 17, 2012. Engel, however, insists that the FDA "banned" these Labeling Terms 18 year before the Final Rule. He is mistaken." Id at 455.

B, page 5 of 81, page 6 of 81, and page 13 of 81). Notably, the *Eckler* court emphasized several times that plaintiff was not alleging “that the SPF values on Neutrogena's labels were inaccurate,” but plaintiff was instead “asserting that labels for SPF 50+ products omitted what she claims is a material fact, that they provide no added clinical benefit compared to products rated at SPF 50.”

In *Gisvold*, just as in *Eckler*, the plaintiff alleged that “SPF values of over 50 do not provide any increase in clinical benefit over SPF 50 sunscreen products” and that “Merck's SPF 55, 70+, 80 and 100+ representations on its sunscreen products are therefore false, misleading, and reasonably likely to deceive the public.” *Gisvold*, supra at 1200-1201. The Southern District of California held that because plaintiff sought to impose requirements greater than FDCA requirements (i.e. requiring a disclaimer regarding the level of sunscreen effectiveness beyond SPF 50), plaintiff's claims were preempted. Again, plaintiff in the case at bar does not seek to impose requirements that conflict with or go beyond FDCA requirements. Rather, plaintiff simply wants defendant to truthfully set forth the SPF value of its sunscreen so that consumers are not misled. (Exhibit A, Complaint, paragraphs 17-21). As such, plaintiff's claims are not preempted.

The other cases cited by defendant are easily distinguishable. In *Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371 (S.D.N.Y. 2014), plaintiff alleged that defendant should be prohibited from including “Restores Enamel” on its mouthwash label. The court held that plaintiff's claims were preempted because the FDA has not prohibited that verbiage on mouthwash labels and therefore, plaintiff's claims were “imposing a labeling requirement that is not identical with labeling requirements under federal law.” *Id* at 376. And, in *Bimont v. Unilever U.S., Inc.*, 2015 U.S. Dist. LEXIS 119908 (S.D.N.Y. Sept. 9, 2015), notwithstanding

federal regulations relative to properly arriving at product net weight, plaintiff alleged that the net weight labeling on defendant's deodorant is misleading -- notwithstanding defendant's compliance with federal regulations --because some of the deodorant is "embedded under the plastic platform ('bed') on which the deodorant sticks stand" and is thus unusable." In stark contrast, in the matter *sub judice*, plaintiff is not asking the court to prohibit or require additional verbiage on defendant's label. Nor is plaintiff asking the court to find that SPF values should be calculated differently. Plaintiff's state law claims parallel and are consistent with FDCA requirements inasmuch as plaintiff has asserted that defendant failed to accurately set forth the sunscreen's true SPF value. (Exhibit A, Complaint, Paragraphs 17, 20; Exhibit B, page 5 of 81, page 6 of 81, and page 13 of 81). And, plaintiff's claims are predicated on violations of obligations imposed by the FDCA and by, *inter alia*, GBL 349 and 350. (Exhibit A).

As set forth *Lombardo v. Johnson & Johnson Consumer Cos.*, 2014 U.S. Dist. LEXIS 156881, *10 (S.D. Fla. Sept. 9, 2014) and *Corra v. Energizer Holdings, Inc.*, 962 F. Supp. 2d 1207 (E.D. Cal. 2013) claims are not expressly preempted where a defendant's FDCA labeling obligations would remain qualitatively unchanged even if plaintiff prevails. Further, in *Fagan v. Neutrogena Corp.*, 2014 U.S. Dist. LEXIS 2795 (C.D. Cal. Jan. 8, 2014), which involved allegations of sunscreen mislabeling, the court explained:

Defendant argues that plaintiffs' claims are expressly preempted by 21 U.S.C. § 379r, because plaintiffs "seek to impose ingredient listing requirements that are different from those contained in FDA regulations." But if defendants are liable under state law for misleading language contained in the products' principal display panels (PDP) as alleged in the FAC, this liability would not impose any requirement on the listing or description of cosmetic ingredients "that is different from or in addition to, or that is otherwise not identical with" the labeling requirements imposed by FDA regulations. 21 U.S.C. § 379r(a)(2); Defendant argues that plaintiffs seek to impose liability under state law for *non-misleading information* displayed on its products, and that this would effectively impose a requirement on cosmetic labeling that is "different from or in addition to" the FDA regulations. This argument assumes the matter that is in dispute in this case,

namely, that the verbiage "100% naturally sourced sunscreen ingredients" and the like in defendant's PDPs is not misleading. **In contrast, if the language in the PDPs is misleading, as the FAC alleges, then state law liability based on the product labels merely creates a damages remedy for violation of state law requirements that "'parallel,' rather than add to, federal requirements," and hence are not preempted.** In short, plaintiffs' claims, if proved, would simply require Defendant to truthfully state [whether the sunscreen ingredients are 100% naturally sourced] or not sell its products; such relief would not impose a state requirement that is different from or in addition to, or that is otherwise not identical with' that of the FDCA. *Id.* at *1-3. (internal citations and quotations omitted) (emphasis added).

In the case at bar, plaintiff seeks redress for defendant's failure to truthfully set forth the product's SPF value. Accordingly, plaintiff's claims are not preempted.

B. Plaintiff's Claims are not Impliedly Preempted

Defendant asserts that plaintiff's claims are preempted because "adjudicating plaintiff's claims" requires the court to "interpret, apply, and work through the FDCA regulations" that pertain to the SPF testing protocol. This is a cobbled-together argument that is plainly inconsistent with implied preemption jurisprudence.

Smith v. Allmax Nutrition, Inc., 2015 U.S. Dist. LEXIS 171897 (E.D. Cal. Dec. 23, 2015) is instructive. In that case, plaintiff alleged that a dietary supplement had been mislabeled, and plaintiff annexed testing reports to his complaint. Defendant argued that plaintiff's claims were preempted by FDA regulations because, *inter alia*, (1) plaintiff did not allege that he performed testing in accordance with Section 101.9(g)(2); and (2) the test results attached to the complaint show that only a single sample was tested, in violation of Section 101.9(g)(2). The court explained that "Section 101.9(g)(2) requires that the sample for nutrient analysis shall consist of a composite of 12 subsamples (consumer units), taken 1 from each of 12 different randomly chosen shipping cases, to be representative of a lot. The methodology described in section

101.9(g)(2) must be used to determine compliance with the requirements for nutrient content claims." The court rejected defendant's preemption argument and explained:

Plaintiff does not allege that the testing he conducted in support of his claims was done in accordance with the 12-sample method set forth in 21 C.F.R. § 101.9(g)(2) or § 101.36(f)(1). In this case, Plaintiff has included copies of laboratory reports showing the results of the testing conducted on the basis of one sample. Nothing in the reports suggests that the testing was done in accordance with the 12-sample method required by § 101.9(g)(2), and Plaintiff concedes that the testing was not done in accordance with § 101.9(g)(2). However, Plaintiff alleges that testing of the sample showed none of the ingredients were present in the sample. To the extent that other courts have found that supporting a complaint with test results that do not show compliance with the 12 sample methodology implicates preemption, this Court disagrees. Plaintiff does not allege in the complaint that a different methodology is sufficient to prove his claim, but attaches the results of the testing conducted to support his allegations that the Product does not contain the listed ingredients. Rule 8 requires a plaintiff to state sufficient factual detail to allow the Court to reasonably infer that each named defendant is liable for the misconduct alleged. Based upon the allegations in the complaint, the Court can plausibly infer that tests conducted in compliance with the 12 sample methodology would support Plaintiff's allegations that the Product is mislabeled. Plaintiff has not pled a different methodology that would impose a different or more burdensome requirement upon a defendant than those set forth by the FDA...For these reasons, the Court finds that at the pleading stage Plaintiff has alleged a plausible claim for mislabeling due to the absence of [ingredients]. Defendant's motion to dismiss on this ground is denied. *Id.* at * 21. (internal citations omitted)

Here, plaintiff pled and supported his averment that an independent laboratory conducted tests that were "compliant with the FDA testing protocol for SPF validation." (Exhibit A, Complaint, Paragraphs 17). Moreover, notwithstanding defendant's incorrect assertions, plaintiff attached the FDA-compliant test that shows the true SPF metric is 18, not 45. (Exhibit A, Complaint, Paragraphs 17, 20; Exhibit B, page 5 of 81, page 6 of 81, and page 13 of 81). In fact, the testing report annexed to the Complaint indicates that "all specifications regarding test subjects, solar simulators, test protocol and measurement standards complied with requirements

in the 2011 FDA Final Rule,” and -- for the avoidance of doubt -- describes the test protocol in detail. *Id.* Defendant’s chief implied preemption argument should thus be rejected⁷.

Moreover, the baselessness of defendant’s argument is evident from a review of cases with outcomes different than the one in *Allmax Nutrition, Inc.* This is because while the courts indicated that plaintiffs are required to plead that their testing methodology is identical to the FDA’s -- which plaintiff in the matter *sub judice* has unquestionably done -- the courts did not find that plaintiff’s claims were preempted simply because complying with the FDA’s testing methodology was an issue in the case. For instance, in *Dougherty v. Source Naturals, Inc.*, 2015 U.S. Dist. LEXIS 164117 (E.D. Mo. Dec. 8, 2015), the court explained that where a plaintiff challenges the accuracy of product information and determining accuracy requires the use of a FDA testing methodology, the plaintiff must aver that he followed the FDA testing methodology or face dismissal on preemption grounds. *See also Mee v. I A Nutrition, Inc.*, 2015 U.S. Dist. LEXIS 63038 (N.D. Cal. May 13, 2015) (“As each district court to have considered the matter has found, where, as here, an FDA regulation provides that the question of compliance must be determined using the method specified therein, a state law claim that seeks to establish a violation of such regulation by a different methodology is preempted.”); *Salazar v. Honest Tea, Inc.*, 74 F. Supp. 3d 1304, 2014 U.S. Dist. LEXIS 83164, 2014 WL 2593601, at *1, 6 (E.D. Cal. June 10, 2014) (granting motion to dismiss claim that defendant’s teas “did not contain the amount of antioxidants represented on their labels,” where plaintiff failed to allege the

⁷ Plaintiff’s reliance on *Elkind v. Revlon Consumer Prods. Corp.*, 2015 U.S. Dist. LEXIS 63464 (E.D.N.Y. 2015) is misplaced. In that case, plaintiffs alleged that various cosmetic products “are incapable of functioning in the manner that their labeling suggests,” i.e. “Age Defying with DNA Advantage.” Here, however, plaintiff has simply alleged that defendant lied about the SPF value of its product. Accordingly, plaintiff’s state law claims parallel and are consistent with FDCA requirements that an entity accurately set forth a sunscreen’s true SPF value.

"independent testing" on which she relied had been conducted in accordance with § 101.9(g)(2)); *See Vital v. One World Co.*, 2012 U.S. Dist. LEXIS 186203, at *2, 13-18 (C.D. Cal. November 30, 2012) (finding defendant entitled to summary judgment on claim defendant made "overstatement of the magnesium and sodium content" of its coconut water product, where plaintiffs failed to offer evidence to show report on which they relied had been conducted in accordance with § 101.9(g)(2)); *See Burke v. Weight Watchers Int'l, Inc.*, 983 F. Supp. 2d 478, 480, 483 (D. N.J. 2013) (granting motion to dismiss claim alleging defendant's ice cream bars' "calorie content [was] 20%-36% greater than the calorie content listed on the box," where plaintiff, *inter alia*, failed to allege the "independent laboratory tests" on which she relied were conducted in accordance with the methodology set forth in § 101.9(c)(1)(i)).

Defendant also incorrectly argues that plaintiff's claims are preempted because they "are grounded solely upon an alleged violation of the FDCA's labeling requirements." In support of this argument, defendant cites to *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (U.S. 2001). But, *Buckman* involved allegations that the defendant manufacturers "made fraudulent representations to the [FDA] in the course of obtaining [pre-market] approval." 531 U.S. at 344. The Court held that "plaintiffs' state-law fraud-on-the-FDA claims conflicted with, and were therefore impliedly pre-empted by, federal law" because the FDA alone was charged with the pre-market approval process. Here, a pre-market approval process is not at issue. Moreover, as explained by the court in *Rosen v. St. Jude Med., Inc.*, 41 F. Supp. 3d 170, 186 (N.D.N.Y. 2014), "while *Buckman* stated that an alleged violation which exists 'solely from the violation of FDCA requirements' is preempted it made clear that its decision did not conflict with *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (U.S. 1996), which held that "state-law causes of action that 'parallel federal safety requirements' are not preempted."

Here, a plain reading of the Complaint reveals that plaintiff's state law claims parallel and are consistent with FDCA requirements inasmuch as plaintiff has asserted that defendant failed to set forth the sunscreen's true SPF value and that this failure amounts to a violation of obligations imposed by, *inter alia*, GBL 349 and 350. (Exhibit A, Complaint, Paragraphs 17-22).

2. Plaintiff's MMWA Claims must Survive FRCP 12(b) (6) Scrutiny

Defendant advances several arguments in support of its assertion that plaintiff's MMWA claim should be dismissed. The MMWA provides that "a consumer who is damaged by the failure of a supplier, warrantor, or service contractor to comply with any obligation under this chapter, or under a written warranty, implied warranty, or service contract, may bring suit for damages . . .". *Enobakhare v. Carpoint, LLC*, 2010 U.S. Dist. LEXIS 141481 at *8 (E.D.N.Y. Jan. 10, 2011) (quoting 15 U.S.C. § 2310(d)(1)).

Defendant's chief argument is that a statement as to the product's SPF is not a written warranty under the MMWA. There is no legal or logical support for this argument. Pursuant to 15 U.S.C. § 2301(6)(A), the term "written warranty" is defined as: "any written affirmation of fact or written promise made in connection with the sale of a consumer product by a supplier to a buyer which relates to the nature of the material or workmanship and affirms or promises that such material or workmanship is defect free or will meet a specified level of performance over a specified period of time." And, it is well-settled that if a product does not affirm or promise (1) that it is defect free or (2) will meet a specific level of performance, then it is not a written warranty within the meaning of the MMWA. *Brady v. Basic Research, L.L.C.*, 101 F. Supp. 3d 217, 234 (E.D.N.Y. 2015). Incredibly, defendant appears to be arguing that an SPF metric does

not amount to an affirmation that the sunscreen will meet a specified level of performance over a specified time. This argument is advanced notwithstanding the FDA's statements that

The SPF value indicates the level of sunburn protection provided by the sunscreen product. All sunscreens must be tested according to an SPF test procedure. The test measures the amount of ultraviolet (UV) radiation exposure it takes to cause sunburn when a person is using a sunscreen in comparison to how much UV exposure it takes to cause a sunburn when they do not use a sunscreen. The product is then labeled with the appropriate SPF value indicating the amount of sunburn protection provided by the product. *Higher SPF values (up to 50) provide greater sunburn protection.* Because SPF values are determined from a test that measures protection against sunburn caused by ultraviolet B (UVB) radiation, SPF values only indicate a sunscreen's UVB protection. (emphasis added).

Spending time in the sun increases a person's risk of skin cancer and early skin aging. To reduce these risks, consumers should regularly use a Broad Spectrum sunscreen with an SPF value of 15 or higher in combination with other protective measures such as: Limiting time in the sun, especially between the hours of 10 AM and 2 PM when the sun's rays are the strongest. Wearing clothing to cover skin exposed to the sun (long-sleeved shirts, pants, sunglasses, and broad-brimmed hats) when possible. Using a water resistant sunscreen if swimming or sweating. Reapplying sunscreen, even if it is labeled as water resistant, at least every 2 hours. (Water resistant sunscreens should be reapplied more often after swimming or sweating, according to the directions on the label.)

(Exhibit A, Complaint, Paragraph 7, footnote 3).

Despite the FDA's plain language about SPF values affirming that sunscreen meets a specified level of performance over a specified time, defendant argues that SPF levels are actually like "All Natural" verbiage on bags of potato chips. To that end, defendant relies heavily on *In re Frito-Lay N. Am., Inc.*, 2013 U.S. Dist. LEXIS 123824 (E.D.N.Y. Aug. 29, 2013), where the court indicated that "All Natural" statements on bags of potato chips are "at most, product descriptions." *Id.* at * 56. The *In re Frito-Lay* case is inapposite. Whereas "All Natural" arguably enables a reasonable consumer to conclude that the product does not contain synthetic ingredients, SPF-45 is the equivalent of a promise that a consumer who purchases and

applies the sunscreen can be assured of a certain level of UV radiation protection for a certain time period. Accordingly, plaintiff's MMWA claim survives FRCP 12 (b) (6) scrutiny⁸.

Defendant also argues -- without any case law citations -- that the MMWA claim is "independently barred" under section 2311 (d) of MMWA. But, as the court explained in *Kanfer v. Pharmacare US, Inc.*, 2015 U.S. Dist. LEXIS 150105 (S.D. Cal. Nov. 4, 2015), "[w]hether § 2311(d) precludes plaintiff's MMWA claim is better suited for a [post discovery dispositive motion], when the record is more fully developed and the parties further analyze the statutory scheme under the facts of the case."

Finally, defendant asserts that the MMWA must be dismissed because the Complaint does not make reference to individual claims exceeding \$25. But, it is well-settled that the Class Action Fairness Act of 2005 eliminated the stringent Magnuson-Moss jurisdictional requirements, including the 100-plaintiff requirement and the over-\$25 requirement. *See Weisblum v. Prophase Labs, Inc.*, 88 F. Supp. 3d 283 (S.D.N.Y. 2015) ("the vast majority of courts have held that, where its conditions are met, CAFA provides an alternative basis for jurisdiction without regard for the MMWA. The Court agrees with the weight of authority, and finds that Plaintiffs' MMWA claims may go forward."), citing *Kuns v. Ford Motor Co.*, 543 Fed. Appx. 572 (6th Cir. Ohio 2013); *Birdsong v. Apple, Inc.*, 590 F.3d 955, 957 n.1 (9th Cir. 2009); *In re Sony Vaio Computer Notebook Trackpad Litig.*, No. 09-CV-2109 (BEN) (RBB), 2010 U.S. Dist. LEXIS 115142, at *4 (S.D. Cal. Oct. 28, 2010); *Chavis v. Fid. Warranty Servs., Inc.*, 415 F. Supp. 2d 620, 626 (D.S.C. 2006).

⁸ Defendant also argues that the MMWA claim fails inasmuch as it is derivative of the state law warranty claims which are preempted. As set forth in detail above, plaintiff's state law claims are not preempted and therefore the MMWA claim must survive.

3. Plaintiff has Plausibly Alleged Actionable Misconduct by Defendant

Defendant argues that the court should dismiss the Complaint because, notwithstanding the Complaint allegations and the verbiage within plaintiff's testing report annexed to the Complaint, it was somehow "not performed in accordance with the FDA testing protocol."⁹ Defendant also argues that it has tests of its own that show the product's SPF is indeed 45, and that the court should consider defendant's tests in determining that plaintiff's test is invalid and that his claims are, therefore, implausible. But, the cases cited by defendant are inapposite. For instance, defendant cites *Samuels v. Greenberg*, 2015 U.S. Dist. LEXIS 128221 (E.D.N.Y. Sept. 23, 2015) where the court considered documents evidencing the time period for a "demand and refusal" relative to a bible. The court considered this evidence because it pertained to when plaintiff's claims accrued, and said "it bears emphasis that those extrinsic materials were submitted by plaintiffs themselves, not defendants." *Id.* at *32-33.¹⁰ Defendant also cites *L-7 Designs, Inc. v. Old Navy, LLC*, 647 F.3d 419 (2d Cir. N.Y. 2011). But that case involved an alleged breach of contract and an FRCP 12 (c) motion (not a 12(b) (6) motion) wherein a court "considers the complaint, the answer, any written documents attached to them, and any matter of which the court can take judicial notice for the factual background of the case." *Id.* at 422. Defendant also cites *Palm Beach Strategic Income v. Stanley P. Salzman, P.C.*, 2011 U.S. Dist. LEXIS 46867 (E.D.N.Y. May 2, 2011), in which the court found that a plaintiff actively misled the court about the true source of a wire transfer at issue in the litigation and had the correct wire transfer information in its possession at the time it actively misled the court.

⁹ The court need only review the plain language of the test report annexed to the Complaint to see that defendant's statement is false. (Exhibit B, page 5 of 81, page 6 of 81, and page 13 of 81).

¹⁰ Defendant also cites *Silverman v. Unum Group*, 2015 U.S. Dist. LEXIS 99714 (E.D.N.Y. July 30, 2015). But, in that case, the court considered an ERISA plan between plaintiff and defendant -- though it had not been annexed to the complaint -- in deciding whether to dismiss a complaint seeking long-term disability benefits and alleging that his claim for benefits was calculated improperly and terminated early.

Contrary to defendant's assertion, not annexing defendant's flawed¹¹ reports to the Complaint does not in any way undermine plaintiff's claims. Given plaintiff's well-pled allegations buttressed by his own independent testing report, defendant's arguments should be rejected and the motion to dismiss should be denied. A motion to dismiss enables the court "merely to assess the legal feasibility of the complaint, not to assay the weight of the evidence which might be offered in support thereof." *Szymczak v. Nissan N. Am., Inc.*, 2011 U.S. Dist. LEXIS 153011, at *18 (S.D.N.Y. Dec. 16, 2011). When deciding a motion to dismiss, the Court must accept all well-pleaded allegations as true and draw all reasonable inferences in favor of the pleader. *Hishon v. King*, 467 U.S. 69, 73 (1984). The claims must contain the grounds upon which the claim rests through factual allegations sufficient "to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Further, a plaintiff is obliged to buttress its claims with factual allegations that allow the court to draw the reasonable inference that defendant is liable for the conduct alleged. *Ashcroft v. Iqbal*, 556 U.S. 662, 129 (2009). The Supreme Court cautioned that "a well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and 'that a recovery is very remote and unlikely.'" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007). In the case at bar, plaintiff has easily met the pleading burden imposed by *Iqbal* and *Twombly*.

Moreover, whether testing results support a plaintiff's claim is an issue of fact that cannot be resolved within the context of a motion to dismiss. In *Quinn v. Walgreen Co.*, 958 F. Supp. 2d 533, 544 (S.D.N.Y. 2013), the court declined to consider on a motion to dismiss whether the plaintiffs' studies supported their allegations, reasoning that a motion to dismiss is not the right time to weigh the evidence. Similarly, in *Hughes v. Ester C Co.*, 930 F. Supp. 2d 439, 461-62

¹¹ The flaws within the reports will be the subject of expert discovery.

(E.D.N.Y. 2013), the court held that the weight that should be afforded to any particular study cannot be decided on a motion to dismiss. Insofar as defendants want to debate whether their tests refute, negate, or undermine plaintiff's test or whether defendant's tests are flawed or valid, this debate can be addressed during the expert phase of the litigation when the court can fulfill its gatekeeper function.

4. There is no Basis to Stay Discovery

Defendant boldly proclaims that it has made a strong showing that all of plaintiff's claims lack merit and that discovery should therefore be stayed. Plaintiff respectfully disagrees with defendant's characterization of its own motion. Courts in the Second Circuit do not grant motions to stay simply because a defendant has filed a non-frivolous motion to dismiss. *See Diaz v. Local 338 of the Retail, Wholesale Dep't Store Union*, 2014 U.S. Dist. LEXIS 124394, *4 (E.D.N.Y. Sept. 3, 2014) (explaining that defendant has not shown good cause for staying discovery.) *See Chesney v. Valley Stream Union Free Sch. Dist. No. 24.*, 236 F.R.D. 113, 115 (E.D.N.Y. 2006) ("Under Federal Rule of Civil Procedure 26(c), a district court may stay discovery during the pendency of a motion to dismiss for 'good cause shown.'" "[T]he mere filing of a motion to dismiss the complaint does not constitute 'good cause' for the issuance of a discovery stay[.]); *Spencer Trask Software and Information Services. LLC v. RPost International Ltd.*, 206 F.R.D. 367, 368 (S.D.N.Y. 2002) ("Pursuant to Rule 26(c) of the Federal Rules of Civil Procedure, a court has discretion to stay discovery 'for good cause shown.'"); *see also Hong Leong Finance Ltd. (Singapore) v. Pinnacle Performance Ltd.*, 297 F.R.D. 69, 72 (S.D.N.Y. 2013) [A] motion for a stay [must] be supported by substantial arguments for dismissal... or-in what we view as an equivalent formulation-that there has been a strong showing that the plaintiff's claim is unmeritorious." (quotations and citation omitted).

Here, defendant has failed to show that its brief constitutes good cause for staying discovery. Moreover, given that this case involves an ongoing business deception that has the potential to adversely impact the health of defendant's consumers, there is a strong rationale for accelerating discovery.

III. CONCLUSION

For the reasons set forth above, plaintiff respectfully requests that the court deny defendants' motion in its entirety.¹²

Dated: February 19, 2016

THE SULTZER LAW GROUP, P.C.

By: /s/ Joseph Lipari

Jason P. Sultzer, Esq. (Bar ID #: JS4546)
Joseph Lipari, Esq. (Bar ID #: JL3194)
Jean M. Sedlak, Esq. (Bar ID #: JS4895)
85 Civic Center Plaza, Suite 104
Poughkeepsie, New York 12601
Tel: (845) 483-7100
Fax: (888) 749-7747
sultzerj@thesultzerlawgroup.com
Counsel for Plaintiff and the Class

¹² If the Court does not deny Defendant's motion to dismiss in its entirety, Plaintiff hereby respectfully requests leave to amend the Complaint pursuant to, *inter alia*, FRCP 15 (a) (2). See e.g. *Pangburn v. Culbertson*, 200 F.3d 65, 70 (2d Cir. 1995) ("leave to amend should be freely granted").